Virginia Department of Social Services
Institutional Review Board

REQUEST FOR WAIVERS OF INFORMED CONSENT

(To be submitted with "Request for Review and Clearance of Human Subjects Research")

Under special circumstances, Principal Investigators may request one of two kinds of waivers to obtain written informed consent from research subjects. *These waivers will be given only when there are compelling reasons to do so.*

The first is a waiver of written documentation, where informed consent is obtained orally. With this waiver, the investigator is required to read or provide the informed consent form to a participant but does not need to obtain the participant's signature on the consent form. Examples when this waiver might be applicable include some Internet or telephone surveys or when signing the consent form might have negative consequences for the subject.

The second is a waiver of informed consent itself. With this waiver, the investigator is not required to give, or read, the informed consent form to a participant. This waiver may be approved by the IRB if the criteria given below are met.

Please check which type of consent waiver is being requested:

☐ **Waiver of written documentation** ☐ **Waiver of informed consent**

In order for your request to be considered, please answer fully each of the following questions. Make sure that each response includes thorough explanation and description. Please provide supporting documentation, as appropriate.

1. Will the research in its entirety involve more than minimal risk to participants? Identify the risk.

2. Why is it practical to conduct the research without the waiver/alteration?

3. Will waiving/altering informed consent adversely affect subjects, their rights, or their welfare? Please explain.

4. Will pertinent information be provided to the subjects later, if appropriate? If yes, when?

5. Can the research be conducted practicably without access to and use of the protected health information?

6. Are the privacy risks to individuals whose protected health information is to be used or disclosed reasonable relative to: (a) the anticipated benefits to the individuals, if any, and (b) the importance of the knowledge that may reasonably be expected to result from the research?

7. Is there an adequate plan to protect the identifiers from improper use and disclosure? Briefly, explain the plan.

8. Is there an adequate plan to destroy the identifiers at the earliest opportunity, consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law?

If submitting an electronic copy of this form and supporting documentation, please send to: irb@dss.virginia.gov. If mailing paper copies of the completed form and other documentation, please send to: IRB Coordinator, Institutional Review Board / Office of Research, Virginia Department of Social Services, 7 North Eighth Street, 5th Floor, Richmond, Virginia 23219-3301.